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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,310	08/31/1999	KOJI UKAI	425-736P	2449

2292 7590 10/21/2004

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,310	UKAI ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11,13-18,20-23,25,26,28-30 and 33-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11,13-18,20-23,25,26,28-30 and 33-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/13/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendments and response filed 07/26/04. Accordingly claims 1-4, 6-11, 13-18, 20-23, 25-26, 28-30 and 33-43 are pending.

Claim 28 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 22. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant was reminded of a need for correction of typographical errors in claims, especially the names of medicaments in claims such as 37-38. In response applicant requested clarification of the misspelled words. All terms need to be verified and compared with the list of drug components in the specification (page 3). A few examples of such terms include chiclopidine, maprotyrine, iphenbrozyl, tertrate, sulpirin, azerastine, etc.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 10, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 10 and 17 are vague and indefinite for reciting "a medicine for improving metabolism of a brain circulation". It is not clear what class of medication fits into this category and what function they have.

Claims are drawn to a composition comprising a basic medicine, having an unpleasant taste and an acidic polysaccharide, where the two agents form an electric interaction, method of preventing the unpleasant taste and method of manufacturing the composition. Examples of the basic medicinal agents include antibiotics and examples of polysaccharides include carrageenan and xanthan gum.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-10, 14-17, 21 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Drug Information for Vantin®.

Drug information for Vantin® discloses that cefpodoxim is an antibiotic (which meets the limitation of a basic medicine) available in powder for suspension or tablet form. The active agent is mixed with other agents including carrageenan (which meets the limitation of an acidic polysaccharide), maltodextrin, natural and artificial flavoring, etc.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 6-9, 13-16, 20-22, 25, 28-30 and 39-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Diehl (5,612,026).

Diehl discloses drink mix compositions comprising a therapeutically effective dose of an anionic exchange resin, from about 0.05 to about 1.25g of xanthan gum and an edible, water soluble salt (col. 2, lines 13-17). The anion exchange resin means any resinous material having cationic moieties, such as *cholestyramine* and *colestipol* hydrochloride, both of which are strongly basic anion exchange resins (col. 3, lines 15-30). Diehl also discloses that edible water soluble salts MAY be added (col. 3, lines 48-62). Other materials including bulking agents and carriers may be added. Such materials can be oligosaccharides and polysaccharides (col. 5, lines 20-45).

Diehl also discloses a method of preparing the said formulations, where cholestyramine, xanthan gum and maltodextrin are charged and allowed to mix (col. 6, lines 45-67).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-4, 10-11, 17-18, 23, 26, 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diehl (5,612,026) in view of Drug information for Vantin® (PDR- 1995).

Diehl, discussed above, lacks specific disclosure on other basic medicines for the said formulation.

Drug information for Vantin® discloses that cefpodoxim is an antibiotic available in powder for suspension or tablet form. The active agent is mixed with other agents including natural and artificial flavoring, maltodextrin, carrageenan, etc.

Diehl teaches the benefit of mixing an anion exchange resin with an acidic polysaccharide to mask the unpleasant taste, and Drug information for Vantin® teaches the need for masking bitter taste of antibiotics such as cefpodoxim (by adding flavors and coating). Thus it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted one basic active agent for the other in order to benefit from the masking properties for more medications with unpleasant taste. Furthermore, one of ordinary skill would be motivated to look for other suitable medicinal components with unpleasant taste and to implement the same method for them in order to provide the same benefit for more patients.

Claims 1-4, 6-11, 13-18, 20-23, 25-26, 28-30 and 33-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tai (5,013,557).

Tai discloses taste masking compositions comprising spray dried microcapsules containing sucralfate and methods for preparing same. The spray dried spheroidal microcapsules comprise in percentages by weight between 1 and 70% of sucralfate and between 30 and 99% of a polymer soluble in gastric fluids (col. 5, lines 30-60). The polymers soluble in the gastric fluids are polymers which bind to sucralfate with taste masking properties and dissolve in gastric fluid. The suitable polymers include alginic acid, carrageenan, xanthan, etc (col. 6, lines 26-55).

Although Tai does not exemplify compositions containing a basic medicine and an acidic polysaccharide, it does teach mixing a medicine with unpleasant taste with a polysaccharide such as carrageenan to mask the taste and thus one or ordinary skill in the art would be motivated to apply the same method to other medications with unpleasant taste in order to provide better tasting medication for patients and increase patient compliance.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Research disclosure 176019 (Derwent WPI Acc No. 78-92367 A/51).

Research disclosure teaches taste masking of beta-lactam antibiotics with cation-exchange resin. The taste-reduced pharmaceutical compositions comprise at least 70% of a mixture of a normally unpleasantly tasting orally active penicillin or cephalosporine that contains an aminoacyl side chain, with a cation-exchange resin, in a ratio of 5:1 to

1:2. The said oral dosage form can be in powder, granules or tablet form. The process of preparation of such formulations includes dissolving and mixing the ingredients in a suitable solvent and drying to form a dry form such as powder.

Response to Arguments

Applicant's arguments, filed 07/26/04, with respect to the rejection(s)of claim(s) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mina Haghighatian
October 04, 2004